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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/550,580	09/23/2005	Martin F. Bachmann	1700.0610001/BJD/WBC	8355

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STERNE, KESSLER, GOLDSTEIN & FOX P.L.L.C.
1100 NEW YORK AVENUE, N.W.
WASHINGTON, DC 20005

EXAMINER	
KINSEY, NICOLE	
ART UNIT	**PAPER NUMBER**
1648	

SHORTENED STATUTORY PERIOD OF RESPONSE	MAIL DATE	DELIVERY MODE
31 DAYS	02/09/2007	PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

If NO period for reply is specified above, the maximum statutory period will apply and will expire 6 MONTHS from the mailing date of this communication.

Office Action Summary	Application No.	Applicant(s)	
	10/550,580	BACHMANN ET AL.	
	Examiner	Art Unit	
	Nicole E. Kinsey, Ph.D.	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 1 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *23 September 2005*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *See Continuation Sheet* is/are pending in the application.

4a) Of the above claim(s) _____ is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☐ Claim(s) _____ is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☒ Claim(s) *1-2,4,6-12,14-15,17-19,21,24-25,27,30,33,35,42,48-49,94-99,102-104,108-112* are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☐ Information Disclosure Statement(s) (PTO/SB/08) Paper No(s)/Mail Date _____.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____ .
5) ☐ Notice of Informal Patent Application
6) ☐ Other: _____.

Continuation of Disposition of Claims: Claims pending in the application are 1,2,4,6-12,14,15,17-19,21,24,25,27,30,33,35,42,48,49,94-99,102-104 and 108-112.

DETAILED ACTION

Election/Restrictions

Restriction is required under 35 U.S.C. 121 and 372.

This application contains the following inventions or groups of inventions, which are not so linked as to form a single general inventive concept under PCT Rule 13.1.

In accordance with 37 CFR 1.499, applicant is required, in reply to this action, to elect a single invention to which the claims must be restricted.

Group I, claims 1,2,4,6-12,14,15,17-19,21,24,25,27,30,33,35,42,48,97 and 111, drawn to a composition or vaccine comprising a virus-like particle; at least one immunostimulatory substance; and at least one antigen or antigenic determinant.

Group II, claims 49,94-96,98,99,102,103,108-110 and 112, drawn to methods for enhancing an immune response and immunizing a subject.

Group III, claim 104, drawn to an isolated polypeptide.

The inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features for the following reasons:

Group III is drawn to a polypeptide and has no technical feature in common with Groups I and II. The technical feature shared among the inventions listed as Groups I and II is a composition comprising a virus-like particle; at least one immunostimulatory substance; and at least one antigen or antigenic determinant. The noted shared technical feature does not provide a contribution over the prior art, as evidenced by the teachings of Kozlovska et al. and Krieg et al.

Kozlovska et al. teaches a virus-like particle composed of RNA bacteriophage QB capsid proteins fused to HBV preS1 and HIV-1 gp120 V3 epitopes.

Kozlovska et al. does not teach the use of immunostimulatory substances. However, Krieg et al. teaches the administration of unmethylated CpG nucleic acids to stimulate and enhance an immune response in a subject to treat HIV. In addition, the Krieg et al. teaches that the CpG nucleic acids can be administered using any delivery vehicle known in the art, including virus-like particles (see paragraph [0129]).

It would have been obvious to one of ordinary skill in the art to modify the virus-like particles of Kozlovska et al. in order to package immunostimulatory CpG nucleic acids. One would have been motivated to do so given the suggestion by Krieg et al. that CpG nucleic acid can be delivered in virus-like particles, and one of ordinary skill in the art would have had a reasonable expectation of success as both components have been used successfully in the art to stimulate and enhance immune responses to antigens and given the fact that viral vectors and virus-like particles (e.g., adenoviral vectors) have been used to deliver nucleic acids.

Further, the courts have said: "It is prima facie obvious to combine two compositions each of which is taught by the prior art to be useful for the same purpose, in order to form a third composition to be used for the very same purpose . . . . [T]he idea of combining them flows logically from their having been individually taught in the prior art." In re Kerkhoven, 626 F.2d 846, 850, 205 USPQ 1069, 1072 (CCPA 1980) (citations omitted) (Claims to a process of preparing a spray-dried detergent by mixing together two conventional spray-dried detergents were held to be prima facie obvious.). In this case, applicants are combining two components, which are known in the art to enhance or stimulate an immune response.

Therefore, the invention as a whole is prima facie obvious to one of ordinary skill in the art at the time the invention was made.

Group I is further restricted as follows: If applicants elect Group I, applicants must also elect one virus-like particle from (a)-(m) from claim 21. Each of the virus-like particles is potentially patentably distinct, because each is different class of virus with different sizes, shapes, number of repeating units, pathology, etc.

This application contains claims directed to more than one species of the generic invention. These species are deemed to lack unity of invention because they are not so linked as to form a single general inventive concept under PCT Rule 13.1.

The species are as follows:

If applicants elect Group I, applicants must also elect

-one antigen out of the antigens recited in (a)-(p) of claim 4, (a)-(i) of claim 7, and (a)-(b) of claim 19 **and** a total of two antigens out of the antigens recited in (a)-(e) of claim 9, (a)-(d) of claim 11, and (a)-(d) of claim 18.

-**NOTE**: Because (a)-(d) of claim 11 each has two antigens (i.e., claim 11(a) (SEQ ID NO:83) is composed of SEQ ID NO:77 and 78 to create the Nef-N56 recombinant), an election from any one of (a)-(d) of claim 11 will constitute an election of two antigens.

-**NOTE**: If applicants elect claim 11(a), claim 18(a) will also be included for examination. If applicants elect claim 11(b), claim

18(b) will also be included for examination. If applicants elect claim 11(c), claim 18(c) will also be included for examination.

-one virus particle as recited in (a)-(l) of claim 24;

-one immunostimulatory nucleic acid as recited in (a)-(d) of claim 27.

If applicants elect Group III, applicants must also elect one SEQ ID NO listed as (a)-(m) of claim 104.

Applicant is required, in reply to this action, to elect a single species to which the claims shall be restricted if no generic claim is finally held to be allowable. The reply must also identify the claims readable on the elected species, including any claims subsequently added. An argument that a claim is allowable or that all claims are generic is considered non-responsive unless accompanied by an election.

Upon the allowance of a generic claim, applicant will be entitled to consideration of claims to additional species which are written in dependent form or otherwise include all the limitations of an allowed generic claim as provided by 37 CFR 1.141. If claims are added after the election, applicant must indicate which are readable upon the elected species. MPEP § 809.02(a).

The following claim is generic: Claim 1.

The species listed above do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, the species lack the same or corresponding special technical features for the following reasons:.

Each of the antigen species is potentially patentably distinct, as each differs from the others in structure and consequently in immunological properties, and each one requires a separate search.

Each of the particle species is potentially patentably distinct, because each is different in overall size, shape, number of repeating units, spacing between repeating units, and/or primary structure.

Each of the activating substance species is potentially patentably distinct, because each differs in chemical nature from the others and potentially has different effects upon the biological activity of the composition as a whole.

Should applicant traverse on the ground that the species are not patentably distinct, applicant should submit evidence or identify such evidence now of record showing the species to be obvious variants or clearly admit on the record that this is the case. In either instance, if the examiner finds one of the inventions unpatentable over the prior art, the evidence or admission may be used in a rejection under 35 U.S.C. 103(a) of the other invention.

Applicant is advised that a reply to this requirement must include an identification of the species that is elected consonant with this requirement, and a listing of all claims readable thereon, including any claims subsequently added. An argument that a claim

is allowable or that all claims are generic is considered nonresponsive unless accompanied by an election.

Applicant is advised that the reply to this requirement to be complete must include an election of the invention to be examined even though the requirement be traversed (37 CFR 1.143).

Applicant is reminded that upon the cancellation of claims to a non-elected invention, the inventorship must be amended in compliance with 37 CFR 1.48(b) if one or more of the currently named inventors is no longer an inventor of at least one claim remaining in the application. Any amendment of inventorship must be accompanied by a request under 37 CFR 1.48(b) and by the fee required under 37 CFR 1.17(i).

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Nicole E. Kinsey, Ph.D. whose telephone number is (571) 272-9943. The examiner can normally be reached on Monday through Friday from 8:00 am to 5:30 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Bruce Campell can be reached on (571) 272-0974. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

Nicole E Kinsey, Ph.D.
Examiner
Art Unit 1648

Stacy B. Chen 2/8/07

STACY B. CHEN
PRIMARY EXAMINER